

WHAT IS CLAIMED IS:

- 1 1. A system for establishing vascular access over a guidewire, said
2 system comprising:
3 a dilator having a lumen sized to be introduced over a guidewire having a
4 -- pre-selected diameter; and
5 a radially expandable sleeve having a lumen therethrough and an
6 unexpanded diameter, said sleeve being configured to expand to a larger diameter as the
7 dilator is advanced through the lumen of the sleeve.
- 1 2. A system as in claim 1, wherein the dilator is tapered at one end to
2 facilitate advancement through the lumen of the radially expandable sleeve.
- 1 3. A system as in claim 2, wherein the dilator comprises an outer tube
2 and an inner obturator, wherein the obturator has the guidewire lumen and the tapered end
3 and wherein the obturator is removable from the outer tube so that the tube may be left in
4 place within the radially expandable sleeve after expansion.
- 1 4. A system as in claim 1, wherein the radially expandable sleeve has
2 a compliant or elastic structure so that its cross-section will collapse after expansion if the
3 dilator is withdrawn from the lumen of the sleeve.
- 1 5. A system as in claim 4, wherein the radially expandable sleeve
2 comprises a tubular braid.
- 1 6. A system as in claim 5, wherein the tubular braid is a mesh of non-
2 elastic filaments wherein radial expansion causes axial shortening of the braid.
- 1 7. A system as in claim 6, wherein the braid is embedded in or
2 covered by an elastic layer.
- 1 8. A system as in claim 1, wherein the radially expandable sleeve is
2 plastically deformable or has a locking structure so that it retains its expanded diameter
3 after the dilator is withdrawn from the lumen of the sleeve.
- 1 9. A system as in claim 1, wherein the radially expandable sleeve
2 comprises an anti-thrombotic coating.

- 1 10. A system as in claim 1, further comprising a guidewire
- 1 11. A system as in claim 1, further comprising a sleeve introducer
2 having a tapered distal end and a lumen therethrough, said sleeve introduced being
3 configured to receive a guidewire through its lumen and to be received within the lumen
4 of the sleeve, whereby an assembly of the sleeve and sleeve introducer can be formed so
5 that the tapered end of the sleeve introducer can be advanced through the tissue to
6 facilitate entry.
- 1 12. A system as in claim 11, wherein the guidewire has a nominal
2 diameter of 0.89 mm (0.035 in.), the dilator has a lumen diameter of 1 mm (0.4 in.), and
3 the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).
- 1 13. A system as in claim 12, wherein the dilator has an outside
2 diameter in the range from 1.3 mm to 3.3 mm.
- 1 14. A system as in claim 11, wherein the guidewire has a nominal
2 diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.),
3 and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).
- 1 15. A system as in claim 14, wherein the dilator has an outside
2 diameter in the range from 1 mm to 2.5 mm.
- 1 16. A method for establishing vascular access, said method
2 comprising:
3 forming a percutaneous tissue tract to a target blood vessel;
4 positioning a guidewire through the tissue tract;
5 positioning a radially expandable sleeve over the guidewire and through
6 the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue
7 tract, wherein the expandable sleeve is in a narrow diameter configuration; and
8 expanding the expansible sleeve to a larger diameter configuration to
9 provide an access lumen to the blood vessel.
- 1 17. A method as in claim 16, wherein forming the percutaneous tissue
2 tract comprises penetrating a needle through tissue overlying the target blood vessel,

3 passing the guidewire through the needle, and removing the needle from over the
4 guidewire.

1 18. A method as in claim 16, wherein positioning the radially
2 expandable sleeve comprises advancing a sleeve having an outer diameter which is no
3 -- more than 300% of the outer diameter of the guidewire.

1 19. A method as in claim 16, wherein the radially expandable sleeve
2 has a compliant or elastic structure so that its cross-section will collapse after expansion.

1 20. A method as in claim 19, wherein the radially expandable sleeve
2 comprises a tubular braid.

1 21. A method as in claim 20, wherein the tubular braid is a mesh of
2 non-elastic filaments wherein radial expansion causes axial shortening of the braid.

1 22. A method as in claim 21, wherein the braid is embedded in or
2 covered by an elastic layer.

1 23. A method as in claim 16, wherein the radially expandable sleeve is
2 plastically deformable or has a locking structure so that it retains its expanded diameter.

1 24. A method as in claim 16, wherein the radially expandable sleeve
2 comprises an anti-thrombotic coating.

1 25. A method as in claim 24, wherein the radially expandable sleeve is
2 positioned by advancing the sleeve behind a tapered distal tip.

1 26. A method as in claim 16, wherein the guidewire has a nominal
2 diameter of 0.89 mm (0.035 in.), the dilator has a lumen diameter of 1 mm (0.4 in.), and
3 the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).

1 27. A method as in claim 26, wherein the dilator has an outside
2 diameter in the range from 1.3 mm to 3.3 mm.

1 28. A method as in claim 16, wherein the guidewire has a nominal
2 diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.),
3 and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).

1 29. A method as in claim 28, wherein the dilator has an outside
2 diameter in the range from 1 mm to 2.5 mm.

1 30. A method for establishing vascular access, said method
2 comprising:
3 forming a percutaneous tissue tract to a target blood vessel;
4 positioning a guidewire through the tissue tract;
5 positioning a radially expandable sleeve over the guidewire and through
6 the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue
7 tract, wherein the expandable sleeve is in a narrow diameter configuration;
8 introducing a dilator over the guidewire and through the expandable sleeve
9 to increase the diameter of the expandable sleeve to a larger diameter; and
10 removing the dilator wherein the expandable sleeve retains the larger
11 diameter.

1 31. A method as in claim 30, wherein forming the percutaneous tissue
2 tract comprises penetrating a needle through tissue overlying the target blood vessel,
3 passing the guidewire through the needle, and removing the needle from over the
4 guidewire.

1 32. A method as in claim 30, wherein positioning the radially
2 expandable sleeve comprises advancing a sleeve having an outer diameter which is no
3 more than 300% of the outer diameter of the guidewire.

1 33. A method as in claim 30, wherein the radially expandable sleeve
2 has a compliant or elastic structure, wherein the large diameter of the sleeve is maintained
3 by an outer tube of the dilator which remains in place after the dilator is removed.

1 34. A method as in claim 33, wherein the radially expandable sleeve
2 comprises a tubular braid.

1 35. A method as in claim 34, wherein the tubular braid is a mesh of
2 non-elastic filaments wherein radial expansion causes axial shortening of the braid.

1 36. A method as in claim 35, wherein the braid is embedded in or
2 covered by an elastic layer.

1 37. A method as in claim 30, wherein the radially expandable sleeve is
2 plastically deformable or has a locking structure so that it retains its larger diameter after
3 the dilator is withdrawn from the lumen of the sleeve.

1 38. A method as in claim 30, wherein the radially expandable sleeve
2 comprises an anti-thrombotic coating.

1 39. A method as in claim 38, wherein the radially expandable sleeve is
2 positioned by advancing the sleeve behind a tapered distal tip.

1 40. A method as in claim 30, wherein the guidewire has a nominal
2 diameter of 0.89 mm (0.035 in.), the dilator has a lumen diameter of 1 mm (0.4 in.), and
3 the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).

1 41. A method as in claim 40, wherein the dilator has an outside
2 diameter in the range from 1.3 mm to 3.3 mm.

1 42. A method as in claim 30, wherein the guidewire has a nominal
2 diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.),
3 and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).

1 43. A method as in claim 42, wherein the dilator has an outside
2 diameter in the range from 1 mm to 2.5 mm.

1 44. An improved method for establishing vascular access, said method
2 being of the type wherein a tapered dilator is introduced over a guidewire to enlarge a
3 percutaneous tissue tract, wherein the improvement comprises introducing a radially
4 expandable sleeve over the guidewire prior to introducing the dilator and thereafter
5 introducing the dilator through the sleeve, whereby axial forces on the tissue from the
6 dilator are reduced.

1 45. A kit comprising:
2 a radially expandable sleeve having a lumen therethrough and an
3 unexpanded diameter, said sleeve being configured to be introduced over a guidewire and
4 expand to a larger diameter as a dilator is advanced through the lumen; and
5 instructions for use according to claim 44.

1 46. A kit as in claim 45, further comprising a dilator having a lumen
2 sized to be introduced over the guidewire.

1 47. A kit as in claim 46, further comprising the guidewire.

1 48. A kit as in claim 46, further comprising a sleeve introducer having
2 a tapered distal end and a lumen therethrough, said sleeve introduced being configured to
3 receive a guidewire through its lumen and to be received within the lumen of the sleeve,
4 whereby an assembly of the sleeve and sleeve introducer can be formed so that the
5 tapered end of the sleeve introducer can be advanced through the tissue to facilitate entry.

1 49. A kit as in claim 46, further comprising a needle.

1 50. A kit as in claim 46, further comprising a package wherein the
2 sleeve, dilator, and guidewire are contained in the package in a sterile condition.